REMARKS/ARGUMENTS

The Examiner is thanked for the clarity and conciseness of the Office Action and for the citation of the references which have been studied with interest and care.

Claim Rejections - 35 U.S.C. §§ 102 and 103

Claims 5-13 [sic] were rejected under 35 U.S.C. §102(b) as being anticipated by Faltys (US 6,157,861, hereinafter "Faltys"). In Applicant's previous response, claim 8 was canceled; therefore, it is believed that the Examiner intended to renew this rejection with respect to claims 5-7 and 9-13, rather than claims 5-13 as indicated.

Faltys discloses "an automated method of determining a suitable range of stimulus intensity for an implantable cochlear stimulator (ICS). Such method includes the steps of: (1) delivering a test stimulation level to one or more of the intracochlear electrodes of the ICS; (2) measuring a physiological response from the subject; (3) adjusting the stimulation level up or down according to a preprogrammed algorithm, and repeating the measurement until a desired response occurs; and (4) automatically recording the final stimulation level determined by the algorithm and using this value, or a value derived by a predetermined function of the recorded value, to determine the intensity of stimulation to be delivered during the normal operation of the ICS." [Faltys, column 4, line 59 - column 5, line 5.]

Applicant's method for fitting a cochlear implant system addresses deficiencies of prior approaches by accounting for temporal and spatial integration. With reference to amended claim 5, this is accomplished via the repetition of steps (b) through (d) for other groups of electrode contacts, in conjunction with step (f), wherein step (b) comprises applying an amplitude modulated pulse train at a known intensity level and having a rate that mimics live speech to the defined group of electrode contacts. For the Examiner's convenience, claim 5 is recited below.

> 5. (previously presented) A method for fitting a cochlear implant system to a patient, the cochlear implant system having a multiplicity of electrode contacts and means for delivering electrical stimuli to a selected electrode contact or a selected group of electrode contacts, the method comprising steps of:
>
> (a) defining a first group of electrode contacts;
>
> (b) simultaneously applying electrical stimuli of a known intensity level to the defined group of electrode contacts;
>
> (c) adjusting the intensity of the electrical stimuli applied in step (b) until a stapedial reflex criteria of the patient is observed;

(d) recording the intensity of the electrical stimuli that produced the stapedial reflex observed in step (c);

(e) repeating steps (b) through (d) for other groups of electrode contacts; and

(f) using the recorded intensities obtained in step (d) for each group of electrode contacts as parameter settings for controlling the intensity of electrical stimuli thereafter applied through the electrode contacts by the implant system;

wherein step (b) comprises applying an amplitude modulated pulse train at a known intensity level and having a rate that mimics live speech to the defined group of electrode contacts.

Advantageously, when electrical stimuli are applied on multiple electrodes at "live speech" pulse rates, the level at which the stapedial reflex is elicited shows a higher correlation with actual "live speech" comfort levels.

Faltys describes "fitting" or "mapping" individual stimulation pulses generated by an implanted cochlear implant (ICS) to an appropriate dynamic audio range so that the appropriate "loudness" of sensed audio signals is perceived. The cited reference, however, does not disclose or suggest the steps of "(b) simultaneously applying electrical stimuli of a known intensity level to the defined group of electrode contacts", "(d) recording the intensity of the electrical stimuli that produced the stapedial reflex observed in step (c)", and "(f) using the recorded intensities obtained in step (d) for each group of electrode contacts as parameter settings for controlling the intensity of electrical stimuli thereafter applied through the electrode contacts by the implant system". The Examiner has not identified any portion of Faltys that would support a prima facie case of anticipation with respect to this claim; therefore, the rejection of this claim is improper.

Further with respect to claim 6, Faltys does not disclose or suggest that: "the recorded intensities obtained in step (d) for each group of electrode contacts comprise a contour of intensities, and wherein the method further includes the step for grouping all of the electrode contacts into a defined last group of electrode contacts and globally shifting the contour of intensities by applying the electrical stimuli to the last group of electrode contacts and adjusting its intensity until a desired stapedial reflex criteria is observed." The Examiner has not identified any portion of Faltys that would support a prima facie case of anticipation with respect to this claim; therefore, the rejection of this claim is improper.

Further with respect to claim 10, Faltys does not disclose or suggest that: "step (b) comprises applying stimuli derived from input signals selected from a group of input signals comprising: shaped bands of noise whose overall bandwidth is adjustable; modulated bands

of noise whose center frequencies are adjustable; complex tonal stimuli whose spectra and various amplitude components are adjustable; speech tokens whose spectra and amplitude envelopes are well described; and white noise." The Examiner has not identified any portion of Faltys that would support a prima facie case of anticipation with respect to this claim; therefore, the rejection of this claim is improper.

Claims 1-4 and 14-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Maltan (US 6,415,185, hereinafter "Maltan") in view of Faltys.

Maltan discloses a technique for measuring the myogenic evoked response (MER), i.e., an invoked potential occurring between wave 5 of the elicited auditory brainstem response (EABR) at a latency of about 5 to 12 milliseconds following acoustic stimulation. Significantly, Maltan discloses a technique for programming a Cochlear implant system based, in part, on measured evoked potentials that precede the stapedius reflex. In contrast with Faltys, Maltan addresses "a need for alternative ways, other than sensing the stapedius reflex, to obtain objective data that can aid in the setting of the stimulation parameters of a Cochlear stimulation device." [Maltan, column 1, lines 60-63.]

Clearly, there is no disclosure or suggestion in Maltan that it would be desirable to provide: means for observing a stapedial reflex criteria of a patient within whom the cochlear implant system is adapted to be implanted; [or] means for adjusting the intensity of the electrical stimuli applied to each group of electrode contacts until a stapedial reflex criteria of the patient is observed. Maltan expressly teaches away from sensing the stapedius reflex in the first instance.

The Examiner has completely failed to indicate any motivation in either reference for combining or modifying the references; therefore, a prima facie case of obviousness has not been established. The mere assertion by the Examiner that "Maltan expressly teaches the use of techniques for objectively setting stimulation parameters involving the use of special electrodes and/or circuitry *adapted* to sense stapedius reflex" [Office Action, page 2 (emphasis added)] does not constitute a teaching that it would be desirable or even possible to sense stapedius reflex using the Maltan technique. Moreover, this new assertion is inconsistent with the teachings of Maltan (discussed above), as well as the Examiner's other characterizations of the cited reference (e.g., "Maltan is considered to disclose the claimed invention... except for the means for observing a stapedial reflex criteria... [Office Action, page 4].")

Even if it ultimately determined that Maltan and Faltys were properly combined, the collective teachings of these references provide no disclosure or suggestion to one of ordinary

skill in the art that it would be desirable to modify the Maltan technique to utilize the impedance bridge configuration in Faltys for the purpose of observing and adjusting the stapedial reflex. To the contrary, Maltan expressly teaches that "[t]here is a need for alternative ways, *other than sensing the stapedius reflex*, to obtain objective data that can aid in the setting of the stimulation parameters of a Cochlear stimulation device." [Maltan, column 1, lines 60-63.] For the reasons discussed above, it is respectfully submitted that the collective teachings of the cited references fail to disclose or suggest claims 1 and 14.

Further with regard to claim 3, the collective teachings of Maltan and Faltys fail to disclose or suggest that "the pulse trains of electrical stimuli are derived from input signals selected from a group of input signals comprising: (a) shaped bands of noise whose overall bandwidth is adjustable; (b) modulated bands of noise whose center frequencies are adjustable; (c) complex tonal stimuli whose spectra and various amplitude components are adjustable; (d) speech tokens whose spectra and amplitude envelopes are well described; and (e) white noise." The Examiner has not identified any portion of Maltan or Faltys that would support a prima facie case of obviousness with respect to this claim; therefore, the rejection of this claim is improper.

Further with regard to claim 4, the collective teachings of Maltan and Faltys fail to disclose or suggest "forming a final group of electrode contacts that includes all of the electrode contacts in the selected groups of electrode contacts, and delivering the pulse trains of electrical stimuli to the final group of electrode contacts after the pulse trains of electrical stimuli have been delivered to all other groups of electrodes that include less than all of the electrode contacts." The Examiner has not identified any portion of Maltan or Faltys that would support a prima facie case of obviousness with respect to this claim; therefore, the rejection of this claim is improper.

Further with regard to claim 15, the collective teachings of Maltan and Faltys fail to disclose or suggest that "the means for applying electrical stimuli comprises means for generating speech-like stimuli, and means for simultaneously applying the speech-like stimuli to each electrode contact in the group of electrode contacts." The Examiner has not identified any portion of Maltan or Faltys that would support a prima facie case of obviousness with respect to this claim; therefore, the rejection of this claim is improper.

Further with regard to claim 16, the collective teachings of Maltan and Faltys fail to disclose or suggest that "the speech-like stimuli comprise electrical signals derived from input signals selected from a group of input signals comprising: shaped bands of noise whose overall bandwidth is adjustable; modulated bands of noise whose center frequencies are

adjustable; complex tonal stimuli whose spectra and various amplitude components are adjustable; speech tokens whose spectra and amplitude envelopes are well described; and white noise." The Examiner has not identified any portion of Maltan or Faltys that would support a prima facie case of obviousness with respect to this claim; therefore, the rejection of this claim is improper.

Further with regard to claim 17, the collective teachings of Maltan and Faltys fail to disclose or suggest that "the means for observing a stapedial reflex criteria comprises means for visually observing a stapedial reflex." The Examiner has not identified any portion of Maltan or Faltys that would support a prima facie case of obviousness with respect to this claim; therefore, the rejection of this claim is improper.

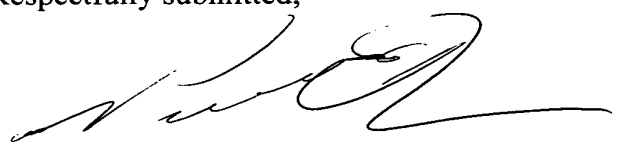
For the reasons discussed above, withdrawal of these rejections is respectfully requested.

CONCLUDING REMARKS

Applicant submits that the application is in condition for allowance. Concurrence by the Examiner and early passage of the application to issue are respectfully requested.

Any additional fees which are required in connection with this communication and which are not specifically provided for herewith are authorized to be charged to deposit account no. 500651. Any overpayments are also authorized to be credited to this account.

Respectfully submitted,



December 21, 2005

Peter L. Holmes
Reg. No. 37,353
Attorney for Applicant

HENRICKS, SLAVIN & HOLMES LLP
840 Apollo Street, Suite 200
El Segundo, California 90245-4737
Telephone: (310) 563-1454
Facsimile: (310) 563-1460